Examiner-Initiated Interview Summary	Application No.	Applicant(s)	
	09/691,237	WELLS ET AL.	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1615	

All Participants:

(1) *Lakshmi S. Channavajjala*.

(2) _____.

Status of Application: *allowance*

(3) _____.

(4) _____.

Date of Interview: *20 December 2006*

Time: _____

Type of Interview:

☒ Telephonic
☐ Video Conference
☐ Personal (Copy given to: ☐ Applicant ☐ Applicant's representative)

Exhibit Shown or Demonstrated: ☐ Yes ☐ No
If Yes, provide a brief description:

Part I.

Rejection(s) discussed:

Claims discussed:

Prior art documents discussed:

Part II.

SUBSTANCE OF INTERVIEW DESCRIBING THE GENERAL NATURE OF WHAT WAS DISCUSSED:
See continuation sheet

Part III.

☐ It is not necessary for applicant to provide a separate record of the substance of the interview, since the interview directly resulted in the allowance of the application. The examiner will provide a written summary of the substance of the interview in the Notice of Allowability.
☐ It is not necessary for applicant to provide a separate record of the substance of the interview, since the interview did not result in resolution of all issues. A brief summary by the examiner appears in Part II above.

LAKSHMI S. CHANNAVAJJALA
PRIMARY EXAMINER

(Examiner/SPE Signature)

(Applicant/Applicant's Representative Signature – if appropriate)

Examiner informed the attorney of record that instant claims will be in condition for allowance upon amending claim 45 to insert the word "film" between "polymeric" and "coating" to avoid the lack of antecedent basis for the coating later in the claim. Attorney agreed with the examiner and will send a clean copy of claims with the suggested amendment, which will be attached to the examiner's amendment.

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"Requested"

FACSIMILE TRANSMITTAL SHEET

Total number of pages including cover letter: 4

To: **Examiner L. S. Channavajjala**
U.S. Patent and Trademark Office

Date: **December 20, 2006**

Facsimile No.: **(571) 273-0591**

Telephone No.: **(571) 272-0591**

From: **Katherine A. Hamer, Esq.**

Serial No.: **09/691,237**

Client/matter number: **1959-7464.1US**

Group Art Unit: **1615**

Message/Comments: **Examiner Channavajjala: Please see attached a clean copy of the claims as amended. Claim 45 has been amended pursuant to our telephone conversation, and claim 46 has been similarly amended for reasons of antecedent basis. Should you have any questions or wish to discuss this matter further, please do not hesitate to contact me.**

Faxed by: AEP Date: 12·20·06 Time: 11:25 am

If you do not receive the complete document, please call (801) 532-1922 as soon as possible

PENDING CLAIMS

Serial No. 09/691,237
TraskBritt No. 1959-7464.1US
Client Ref. No. N-406-US

37. The oral sustained-release pharmaceutical composition according to claim 45, wherein the oral sustained-release pharmaceutical composition releases the active compound at a rate sufficient to maintain a therapeutically effective serum concentration of the active compound for at least 8 hours.

38. The oral sustained-release pharmaceutical composition according to claim 45, wherein the oral sustained-release pharmaceutical composition releases the active compound at a rate sufficient to maintain a therapeutically effective serum concentration of the active compound for at least 12 hours.

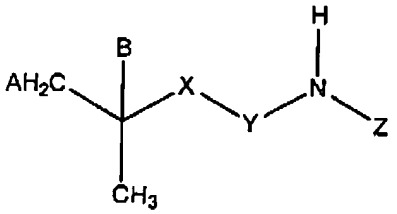
39. The oral sustained-release pharmaceutical composition according to claim 45, wherein the gelling agent comprises xanthan gum.

41. The oral sustained-release pharmaceutical composition according to claim 45, further comprising at least one excipient.

42. The oral sustained-release pharmaceutical composition according to claim 45, wherein the active compound is isovaleramide.

45. An oral sustained-release pharmaceutical composition comprising a core matrix comprising a therapeutically effective amount of an active compound, a gelling agent, and a polymeric film-coating material comprising a mixture of ethyl cellulose and hydroxypropyl methylcellulose that retards access of liquids to the active compound and/or retards release of the active compound through the polymeric film-coating material, wherein the amount of the active compound represents from about 40% to about 70% by weight of the oral-sustained release

pharmaceutical composition, and wherein the active compound is selected from the group consisting of: isovaleric acid, a pharmaceutically acceptable salt of isovaleric acid, a pharmaceutically acceptable ester of isovaleric acid, a compound having the structure:



wherein A = H, CH_3, or OH,

B = H, OH, or CH_3,

X = CH_2, $CHCH_3$, $C(CH_3)_2$, -O-, CH(OH), or -CH_2O-,

Y = -CO-, or –SO_2-, and

Z = H, CH_2CO_2H, or CH_2CONH_2,

and a compound selected from the group consisting of isovaleramide, 2-methylisovaleramide, 3-methylisovaleramide, 2,2-dimethylisovaleramide, 2,3-dimethylisovaleramide, 4-methylisovaleramide, 2,4-dimethylisovaleramide, 3,4-dimethylisovaleramide, 2,2,4-trimethylisovaleramide, 3-hydroxyisovaleramide, 4-hydroxyisovaleramide, 4-hydroxy-3-methyl-isovaleramide, 2-hydroxyisovaleramide, N-(2-acetamido)isovaleramide, 2-methyl-1-propylsulfonamide, 1-methylethyl sulfamate, 2-methyl-1-propyl sulfamate, isopropyl carbamate, and isobutylcarbamate.

46. The oral sustained-release pharmaceutical composition according to claim 45, wherein the polymeric film-coating material further comprises a plasticizer.

47. The oral sustained-release pharmaceutical composition according to claim 45, wherein the oral sustained-release pharmaceutical composition is in the form of a tablet, capsule, or multiparticulate composition.